AMENDMENTS TO THE CLAIMS

2

Claims 1-71 (Cancelled)

- 72. (Currently amended) A method of transferring <u>a plasmid containing a DNA sequence</u> coding for a protein gene into a recipient subject comprising:
 - (a) transfecting <u>autologous</u> somatic cells *in vitro* with the <u>a plasmid containing a</u>

 DNA sequence <u>coding for a protein</u> by chemical or physical techniques to

 introduce the <u>plasmid containing a DNA</u> sequence <u>coding for a protein</u> into the

 cells;
 - (b) screening the resulting transfected somatic cells *in vitro* to select a cell, wherein the selected cell is stably transfected with the <u>plasmid containing a DNA</u> sequence coding for a protein so that the selected cell has the permanent capacity to direct expression of the DNA sequence coding for a protein; and
 - (c) cloning and expanding the selected somatic cell in vitro; and
 - (d) injecting the resulting transfected, <u>isolated</u>, <u>autologous</u>, screened, cloned, and expanded somatic cells into the recipient subject.;

wherein the DNA sequence comprises the gene and a promoter capable of functioning in the somatic cells; and

wherein, following injection of the transfected, screened, cloned, and expanded immortalized somatic cells into the recipient subject, the DNA sequence is incapable of recombining with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

- 73. (Currently amended) The method of claim 72, wherein the somatic cells are human cells.
- 74. (Previously presented) The method of claim 73, wherein the human cells are selected from the group consisting of fibroblasts, myocytes, hepatocytes, kidney capsular cells, endothelial cells, epithelial cells of the gut, and pituitary cells.

75. (Currently amended) The method of claim 73, wherein the <u>plasmid contains a DNA</u> sequence coding for gene encodes a hormone[[,]] or an enzyme, or a receptor.

76. (Currently amended) The method of claim 73, wherein the <u>plasmid contains a DNA</u> sequence coding for gene encodes human growth hormone.

77. (Currently amended) The method of claim 73, wherein the <u>plasmid contains a DNA</u> sequence coding for gene encodes human insulin.

78. (Previously presented) The method of claim 73, wherein the transfection comprises calcium phosphate-mediated transfection, microinjection, electroporation, or DEAE-dextran transfection.

Claims 79-81 (Cancelled)

82. (Currently amended) The method of claim 73, wherein the promoter is plasmid further comprises a regulatable promoter.

83. (Currently amended) The method of claim 73 82, wherein the DNA sequence plasmid further comprises a selectable gene, and wherein the promoter is operably linked to the selectable gene.

84. (Previously presented) The method of claim 73, wherein the screening step further comprises screening the resulting transfected somatic cells *in vitro* to select a cell possessing desired expression properties.

Claims 85-103 (Cancelled)

104. (Currently amended) A method of transferring <u>a plasmid containing a DNA</u> sequence coding for a protein gene into a recipient subject comprising:

4

- (a) providing autologous somatic cells;
- (b) transfecting the somatic cells *in vitro* with <u>a plasmid containing</u> a DNA sequence <u>coding for a protein and further</u> comprising the gene and a promoter capable of functioning in the somatic cells, wherein the gene encodes a gene product, and wherein the somatic cells are stably transfected with the <u>plasmid containing a DNA sequence coding for a protein gene</u> so that the somatic cells have the permanent capacity to direct expression of the <u>DNA sequence coding for a protein gene</u> upon induction of the promoter;
- (c) screening the resulting transfected somatic cells *in vitro* to select a transfected somatic cell, wherein the screening comprises characterizing the transfected somatic cell with respect to expression and regulation of the <u>DNA</u> sequence coding for a protein gene by assaying for translation of the mRNA into protein the gene product;
- (d) cloning and expanding, *in vitro*, the transfected and screened somatic cell selected in step (c) to form the 10⁵ 10¹⁰ transfected, screened, cloned, and expanded somatic cells,
- (e) combining the 10⁵ 10¹⁰ transfected, screened, cloned, and expanded somatic cells with a physiologically acceptable buffer or carrier; and
- (f) injecting the resulting transfected, <u>isolated</u>, <u>autologous</u>, screened, cloned, and expanded cell preparation into the recipient subject.

wherein, following injection of the transfected, screened, cloned, and expanded somatic cells into the recipient subject, the DNA sequence is incapable of recombining with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

105. (Currently amended) The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the transferred plasmid contains a DNA sequence coding for transfected gene encodes human growth hormone.

Docket No.: T0541.70000US06

Application No. 08/465596 Reply to Office Action of July 27, 2005

106. (Currently amended) The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the transferred plasmid contains a DNA sequence coding for transfected gene encodes insulin.

5

- 107. (Currently amended) The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the <u>plasmid containing</u> a DNA sequence <u>coding for a protein</u> integrates into the chromosome of the selected cell.
- 108. (Currently amended) The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the <u>plasmid containing</u> a DNA sequence <u>coding for a protein</u> replicates as an extrachromosomal plasmid.